Business Support International

Amstel 320-I - 1017 AP Amsterdam - The Netherlands Tel + 31-20-428 95 91 Fax + 31-20-428 9429
271 Waldroup Rd - P O Box 457 - Hot Springs, NC 28743 Tel + 1-828-622 7572 Fax + 1-828-622 0264

Mobile 31-(0) 6-51 41 58 39 - bsi@xs4all nl + bsi@wnclink com
Trade Register KvK Amsterdam 33284008
VAT # NL-2067-39-151-B01

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

April 23, 2003

Docket 02N-0534 MDUFMA
Here: Medical Devices User Fees for 510(k) Premarket Notifications

TO WHOM IT MAY CONCERN:

With consternation and shock we received two invoices for $2,187 for two of our clients who submitted premarket notifications in November and December, 2003. When the regulation was published in November 2002 and even now, the **Summary of the Medical Device User Fee and Modernization Act of 2002** contains the following table:

Fee Structure and Initial Fees				
Application	**Fee Structure**	**Initial Fee (FY 2003)**		
	(Percent of Baseline Fee)	**Standard Fee**	**Small Business Applicant** ($30 million threshold) Percent of Standard Fee	Small Business Fee
Premarket application (PMA, PDP, BLA)	Baseline Fee (100%)	$154,000	38%	$58,520
Premarket report	100%	$154,000	38%	$58,520
Panel-track supplement	100%	$154,000	38%	$58,520
Efficacy supplement	100%	$154,000	38%	$58,520
180-day supplement	21.5%	$33,110	38%	$12,582
Real-time supplement	7.2%	$11,088	38%	$4,213

This indicates clearly that large companies have to pay $2,187 for each 510k reviewed in FY 2003, while the applicability of this ruling for small companies will be enacted as of FY 2004.

Under the heading **How Can a Small Business Qualify for Reduced Fees**

[redacted]

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the following table says that 80% of the standard fee will be charged for FY 2004 and subsequent years:

Determination of Small Business Fees

Application	Small Business Fee
• Premarket application (PMA, PDP, BLA)	38% of standard fee
• Premarket report (premarket approval application for a reprocessed device)	
• Panel-track supplement	
• Efficacy supplement	
• 180-day supplement	
• Real-time supplement	
• 510(k)	80% of standard fee for FY 2004 and subsequent fiscal years

And the letter accompanying the invoices says:

We are confident, therefore, that the invoices were issued in error and that the charges will be reversed

In addition, we want to take this opportunity to point your attention to very small companies who have supplied the US market with high quality surgical devices for many decades. To charge them 80%, i.e. $1,750 as of FY 2004, is entirely too high a fee in relationship to their size:

1. Fees

'*Small Companies*' per FDA definition generate prior-year sales up to $30 million. The annual sales of the small foreign manufacturers whom we assist with their FDA compliance activities lie between **1.7%** and **15%** of this threshold amount To charge such tiny companies the same amount as 'small ones' with $30 million sales and only 20% less than billion $ companies, seems directly opposed to the fairness the FDA regulatory organization historically has been trying to achieve in previous rulings. Following is a table with data of a representative sampling of companies surveyed this past week and suggested fees prorated on the basis of total sales:

2002 Total Sales $ million	% of FDA Threshold for 'Small Company' ($ 30 mill.)	# Employees	% of Sales to USA	More Equitable Calculation Based on Size ($2,187)
0.5	1.7%		80%	$ 38
0.65	2.2%		70%	$ 48
1.2	4.0%	10	70%	$ 88
1.5	5.0%	3 full-time 5 part-time	80%	$109
1.76	5.9%	19	>10%	$129
1.9	6.3%	23	60%	$138
2.0	6.9%		12.4%	$150
2.5	8.3%	30	20%	$182
2.5	8.3%			$182
3.5	11.7%	28		$255
4.5	15.0%	24	27.5%	$328

Prorated Fee Based on Sales for Larger Companies

Threshold $30 mill Small Co.	Prorated Factor Based on Total Sales			$2,187
$50 mill	1.67			$3,652
$100 mill	3.33			$7,282
$500 mill	16.67			$36,457

Somehow, a fee of $36,457 for one submission seems inapproriately high for a $500 million sales organization, but the levying of the same fee ($2,187) on tiny manufacturers is much, much more inequitable based on company size and the costs these tiny companies incur as participants in the international regulatory business environment.

2. Special Situation of Small Manufacturers in Southern Germany

The objective for the new ruling is to make the FDA more viable, to speed up the review process and to generally make the medical environment safer and more effective. We seriously doubt that this goal will be reached if the ruling is enforced as presently published.

In southern Germany, within a radius of 15 miles, more than 500 small manufacturers produce precision specialty instruments. They are part of a tradition of more than 150 years of surgical instrument makers that is highly regulated by the German medical device law which also specifies the requirements for becoming a *master surgical instrument maker.* With few exceptions, these firms are family-owned and managed by third and fourth generation family members. 80% have

less than 20 employees, sell between $0.5 and 4.5 million and export up to 80% of their instruments to the United States.

Since the beginning of the last century, these companies have formed a specialized workbench for many US firms who buy their instruments from as many as 65 separate companies and subsequently market them under their own label in the US. The small manufacturers are ISO 9001 and CE certified, must engage consultants for their FDA compliance activities, and bear the development costs of designing innovative new instruments and/or making improvements to traditional ones. If they now must pay the same or 80% of the fees as large companies to obtain US marketing clearance, many may be forced to decide that supplying the US market is no longer a viable option. It is the writer's view that this will be to the detriment of the US patient. This also applies to our English and other small European clients. Please consider the following examples:

Example 1
The cardiovascular branch requested last fall that three separate submissions be submitted for a handful of instruments classified as

- interventional cardiovascular devices
- peripheral vascular devices (only one instrument) and
- circulatory support & prosthetic devices

In past years, only one submission would have been sent in. Even if charged with 'only' 80% of the stipulated fee, the new regulation would cost the company an additional $5,248.80. Adding to that the costs of preparing the submission, these two cost factors alone will add up to more than the estimated annual sales of approx. $10,000 for the devices in question.

Example 2
To be competitive, manufacturers have to offer entire lines of specialty instruments, of which they may sell only 50 – 100 per year. At this volume, the additional cost factor of $2,187 for each classification appears prohibitive.

Example 3
A manufacturer with total sales of $1.5 million has developed unique features to overcome the traditional problem of effectively cleaning Kerrison Rongeurs. His models open wide for cleaning and click into position for safe operation. The hospital staff saves considerable time with reprocessing; the danger of losing screws or not properly reassembling the devices has been eliminated; the procedure has become much safer for surgeon and patient. Other comparative 'improvements' are now on hold and may NOT REACH THE US MARKET if the stipulated fees are not reversed or prorated to reflect company size.

Example 4
A manufacturer specializing in scissors has developed a revolutionary emergency tracheostomy set. In a fraction of the time required for traditional procedures, breathing is restored. Simultaneously, the new design eliminates the danger of injuring the back trachea. This company has several highly innovative developments in process that will not reach the US market if the contemplated fees are imposed

3. Process of Establishing Small Business Status

The regulation stipulates the following steps for 'Small Business' status qualification:

a. Submit certified Federal Income Tax Returns for most recent taxable year
b FDA reviews certification within 60 days. If firm qualifies as small business,
c. It is assigned a Small Business Decision Number and may then submit a 510(k) submission;
d. This process must be repeated each year prior to submitting new premarket notifications.

The tiny companies we represent in several European countries will not have significantly varying total sales from one year to the next. As they are family businesses, there are no affiliates, subsidiaries, and other such business entities that must be taken into consideration.

Financial statements are usually not available for at least 18 months following a business year, as accountants in countries such as The Netherlands and Germany file for extensions with the local tax authorities to even out their workload over the year If made available, the returns would have to be translated into English, adding another cost factor that probably cannot be recovered by the stipulated 20% small business reduction of $437.40. It is also seriously questioned why certified income tax returns are required to establish total sales figures. Such documents appear more appropriate for business acquisition negotiations.

Recommendations
It seems that the proposed procedure for establishing small business status will seriously delay the review process of 510k submissions. Since the objective is to make device clearance more efficient, the writer suggests the use of existing channels in assessing company size:

1 Add a statement to each submission, much like the Truthful and Accurate Statement, in which the owner or general manager of the company and/or their certified accountant certify the sales volume generated during the previous year
2 An alternative would be to change the annual establishment registration form, being sent out routinely each year, to include the sales figure. This

figure should be confidential, however, and must not appear on the FDA establishment registration website.

3 Add the review of financial papers to the FDA Device Inspection checklist to verify information provided under (1) and (2).

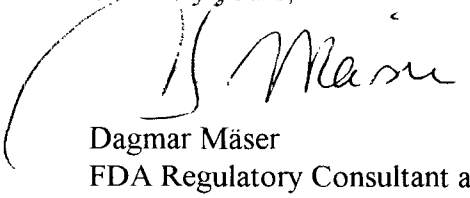
SUMMARY

In summary I respectfully suggest to the Commission:

1. To confirm that no medical device user fee is levied on tiny companies for FY 2003, in conformance with the published tables;
2. To adjust the user fee for FY 2004 on a prorated basis:
   a. higher for large companies
   b. relative to sales volume for tiny companies when compared to threshold small companies with sales of up to $30 million
3 To eliminate the need for certified income tax returns
4 To adjust the procedure for small company status determination either by
   a. using a certified statement on last year's sales or
   b. modifying the annual establishment registration to include this confidential figure

Please do not hesitate to contact me if you require clarification on any points raised above.

Sincerely yours,



Dagmar Mäser
FDA Regulatory Consultant and
FDA Liaison for Very Small Foreign Device Manufacturers